

Memorandum

70059

February 25, 1983

Date

From Chief, Technology & Evaluation Branch, HFF-436

Subject Proposed Order to List D&C Red No. 33.

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To Patricia McLaughlin

Division of Food and Color Additives, HFF-334

Through: Associate Director for Physical Sciences, HFF-400 *R.M. Laff*
Director, Division of Color Technology, HFF-430 *K.S. Smith*

I do not believe the proposed specifications are adequate to assure that future samples of D&C Red No. 33 will be similar to the sample that was tested toxicologically.

The proposed specification for subsidiary colors is non-specific and is enforced using a method developed for determining only Chromatropene 2R. This proposed specification would permit as much as 5% of the suspected carcinogens, p-aminoazobenzene and 1,3-diphenyltriazenes.

Chromatropene 2R is the only subsidiary color in D&C Red No. 33 that has been identified. However, we know that other colored compounds are present in commercial samples of the color.

If we changed the specification from subsidiary colors to Chromatropene 2R, we would then have to rely on the now "toothless" GMP specification to prevent samples containing unidentified substances including the above named suspected carcinogens from entering consumer products.

Of course my concern is deprived of significance if the color additive is determined to be safe when containing 5% or more of those suspected carcinogenic substances or other possible "subsidiary colors".

William B. Link
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cc: HFF-152
HFF-158
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